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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,597	04/30/2001	Antoni P. Tomsia	IB-1627	3236

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EXAMINER	
CHRISS, JENNIFER A	

ART UNIT	PAPER NUMBER
1794	

MAIL DATE	DELIVERY MODE
07/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/845,597	TOMSIA ET AL.	
	Examiner	Art Unit	
	JENNIFER A. CHRISS	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,8-12,20-28 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,8-12,20-28 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. In view of the amendment and 1.132 Affidavit pursuant to 37 CFR 41.50(b)(1) filed on May 27, 2009, PROSECUTION IS HEREBY REOPENED.

2. To avoid abandonment of the application, appellant must exercise one of the following two options:

a. (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

b. (2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

3. A Director has approved of reopening prosecution by signing below:

4. The 1.132 Affidavit is sufficient to overcome the new ground of rejection presented by the Board of claims 1, 3, 5, 8 – 12 and 20 – 28 under 102(a) as applicant indicates that the article entitled “Glass-hydroxyapatite coatings on titanium-based implants" describes Applicant's own work. As such, the 35 USC 102(a) and the 35 USC 103(a) rejections are withdrawn.

5. The claim amendments filed on May 27, 2009 incorporating the limitations of previous claim 3 overcomes the 35 USC 102(b) rejection as anticipated by the article entitled "HA-bioactive glass composites: High temperature reactivity and 'in-vitro' behavior".

6. However, after further consideration of the publications provided in the IDS of December 2, 2002, the Examiner sets forth new rejections below.

Prior Art vs. Provisional Application

7. Applicants filed a provisional application 60/201,556 on 05/01/2000. The examiner wishes to remind the applicants of the grace period provision in 35 USC 102 which gives the applicant one year to file a patent application from describing the invention in a printed publication. Applicants own work publicly disclosed prior to 5/1/1999 (over one year prior to filing for a patent in the US), may be used as prior art under 35 USC 102(b) and thereby constitutes a statutory bar.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Disclosure on a website is considered to be a printed publication. Furthermore, It is held that disclosure at a conference may constitute prior art: ***In re Klopfenstein***, No. 03-1583 (Fed. Cir. August 18, 2004), the federal circuit affirmed the rejection of an application under § 102(b), holding that a slide presentation printed and pasted onto poster board, when made sufficiently publicly accessible, constituted a "printed publication" under 35 U.S.C. § 102(b).

8. Applicant's provisional application comprises a number of articles in which there appears to be printed disclose of the invention before May 1, 1999.

a. The article by Gomez-Vega et al. entitled "A multilayer approach to fabricate bioactive glass coatings on Ti alloys" is available under many different forms. It should be noted that the published form of the article in the Symposia Proceedings published February 2000 falls within Applicant's grace period; this particular version was provided in the IDS submitted on December 2, 2002 and as a part of the provisional application 60/201,556. However, additional versions of public dissemination are available as follows and are relied upon as prior art:

i. The paper under the same title was presented at the MRS 1998 Fall Meeting on Tuesday, December 1 at 3:30 pm.

ii. The paper under the same title was made available via the Lawrence Berkeley National Laboratory website with a publication date of December 1, 1998.

b. Pazo et al. "Silicate glass coatings on Ti-based implants," Acta Mater, Vol 46 (No. 7), p. 2551 - 2558, (1998).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 8 – 11 and 20 – 28 are rejected under 35 U.S.C. 102(b) as being anticipated by the paper entitled "A multilayer approach to fabricate bioactive glass coatings on Ti alloys" presented at the MRS 1998 Fall Meeting on December 1, 1998 or alternatively the paper entitled "A multilayer approach to fabricate bioactive glass coatings on Ti alloys" available via Lawrence Berkeley National Laboratory with a publication date of December 1, 1998.

The paper discusses coating a titanium-based alloy (Ti6Al4V) substrate with glass (page 349 or page 2 of 6) having the following compositions:

Table I Composition and main properties of the synthesized glasses

	Composition (wt%)						α	Ts
	SiO_2	Na_2O	CaO	MgO	P_2O_5	K_2O	(10^{-6} °C^{-1})	(°C)
6P50	49.8	15.5	15.6	8.9	6.0	4.2	12.2	560
6P53	52.6	10.4	18.0	10.2	6.0	2.8	11.5	608
6P55	54.5	12.0	15.0	8.5	6.0	4.0	11.0	602
6P57	56.5	11.0	15.0	8.5	6.0	3.0	10.8	609
6P61	61.1	10.3	12.6	7.2	6.0	2.8	10.2	624
6P68	67.7	8.3	10.1	5.7	6.0	2.2	8.8	644

α = Coefficient of thermal expansion (measured between 200 and 400°C)
Ts = Softening point

The paper also discusses bi-layered coatings (page 350 or page 3 of 6) as shown below:

Table II Multilayered glass coatings results

Glass layers	Thickness (μm)	Firing T (°C)	Coating results
6P68/6P55	30/20	840	Cracked
6P61/6P55	30/20	820	Good
6P57/6P53	30/20	800	Good
6P57/6P50	30/20	800	Cracked
6P57/6P53/6P50	30/10/10	800	Cracked
6P57/(6P57+HA)	30/20*	800	Good

*HA:6P57 = 50 wt%

The paper notes that depositing a glass-HA mixture as a layer on top of a glass that gives good adhesion to the metal (page 351 or page 3 of 6). It should be noted that claim 1 requires "up to 50 wt% of Ha particles". It is the position of the examiner that "up to" includes zero so the HA particles are optional and a reading of the present Specification indicates that this position is accurate. The glass composition of 6P50, 6P53, 6P55, 6P57 and 6P61 all anticipate the claimed glass composition of claim 1. The multilayered glass coating combination of 6P61/6P55 anticipates the layers of claim 9. The multilayered glass coating combination of 6P57/6P50 anticipates the layers of claim 10. The multilayered glass coating combination of 6P57/(6P57+HA) anticipates the layers of claims 11, 20 – 21, 23, 25 and 27. The paper notes that the coating operation can be repeated as many times as the desired number of layers (page 349 or page 2 of 6) which implies that more coating glass layers than two can be present resulting in Applicant's claimed "first intermediate layer" and "second intermediate layer". It should be noted that the term "about" in the claims is interpreted as +/- 5wt%.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 5, 12 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the paper entitled "A multilayer approach to fabricate bioactive glass coatings on Ti alloys" presented at the MRS 1998 Fall Meeting on December 1, 1998 or alternatively the paper entitled "A multilayer approach to fabricate bioactive glass coatings on Ti alloys" available via Lawrence Berkeley National Laboratory with a publication date of December 1, 1998 in view of the article entitled "Novel Bioactive Functionally Graded Coatings on Ti6Al4V" by Gomez-Vega et al published March 1, 2000.

The paper and presentation entitled "A multilayer approach to fabricate bioactive coatings on Ti alloys" teach the claimed invention above but fail to disclose that the first layer, first intermediate layer and the second intermediate layers have a HA gradient as required by claim 5 and SiO2 gradient as required by claim 30, where the concentration in the first layer is the lowest, the highest in the second intermediate layer with the first intermediate layer having a concentration between the other two.

The article entitled "Novel Bioactive Functionally Graded Coatings on Ti6Al4V" discusses graded bioactive glass coatings (paragraph 2, page 1). The article indicates that layers of glass with different compositions and mixtures of glass and HA were sequentially deposited on the metal and fast-fired under the conditions that provide

optimum adhesion for glass in contact with the alloy (page 3, paragraph 2). The article notes the use of step-wise variations of the glass components through each layer of the coating. The article indicates that by creating a SiO2 gradient among the layers the adjacent layers can infiltrate due to the different softening points. The graded coatings reduce thermal stresses, enhance coating stability and have excellent adhesion to the metal layer (page 3, paragraphs 1 - 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a SiO2 or an HA gradient in the first layer, first intermediate layer and the second intermediate coating layers as suggested by the article entitled "Novel Bioactive Functionally Graded Coatings on Ti6Al4V" in the composite of "A multilayer approach to fabricate bioactive glass coatings on Ti alloys" motivated by the desire to create a Ti-based coated alloy having reduced thermal stress, enhanced coating stability and excellent adhesion to the metal layer.

As to claim 12, Applicant requires that the first layer, first intermediate layer and the second intermediate layers have a specific glass composition. It should be noted that this composition is the composition described by "A multilayer approach to fabricate bioactive glass coatings on Ti alloys" as 6P61. Furthermore, the article teaches using up to 50% by weight of HA particles in the top layer (page 351 or page 3 of 6). Additionally, the article notes that the coating operation can be repeated as many times as the desired number of layers (page 349 or page 2 of 6). As the secondary reference article, "Novel Bioactive Functionally Graded Coatings on Ti6Al4V", note that multiple layers

allows the ability to make graded coating to reduce thermal stresses, enhance coating stability and provide excellent adhesion to the metal layer, it would have been obvious to create a composite with three coating layers each having the same disclosed glass composition with the first layer having 50% by weight of HA particles as all of the claimed elements are known and one skilled in the art could have combined the elements as claimed by known methods with no change to their respective functions and the combination would have yielded the predictable result of enhanced coating stability, reduced thermal stress and excellent adhesion of layers.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER A. CHRISS whose telephone number is (571)272-7783. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 6 p.m., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on 571-272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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